BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0949; FRL-9906-47]

Triflumizole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of triflumizole in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0949, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0949 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0949, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 15, 2013 (78 FR 11126) (FRL-9378-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8119) by IR-4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The petition requested that 40 CFR 180.476 be amended by establishing tolerances for residues of the fungicide triflumizole, 1-[1-((4-chloro-2-(trifluoromethyl) phenyl)imino)-2propoxyethyl]-1*H*-imidazole, in or on berry, low growing, subgroup 13–07G at 2.0 parts per million (ppm); fruit, pome, group 11–10 at 0.5 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.5 ppm; and tomato at 1.5 ppm. That document referenced a summary of the petition prepared by Chemtura, the registrant, which is available in the docket, *http://www.regulations.gov*. A comment was received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

In the **Federal Register** of October 25, 2013 (78 FR 63938) (FRL-9901-96), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), which amended the notice of filing published on February 15, 2013, for the pesticide petition (PP 2E8119) submitted by IR-4, 500 College Road East, Suite 201W., Princeton, NJ 08540. The modified petition requested that 40 CFR 180.476 be amended by establishing

tolerances for residues of the fungicide triflumizole, 1-[1-((4-chloro-2-(trifluoromethyl) phenyl)imino)-2propoxyethyl]-1*H*-imidazole, in or on berry, low growing, subgroup, 13–07G at 2.0 ppm; fruit, pome, group 11–10 at 0.5 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2.5 ppm; and tomato at 1.5 ppm. The petition also requested that EPA amend the existing tolerance by modifying the vegetable, cucurbit, group 9 tolerance from 0.5 ppm to 0.8 ppm and, upon approval of the tolerances stated in this paragraph, by removing established tolerances for apple at 0.5 ppm; grape at 2.5 ppm; pear at 0.5 ppm; and strawberry at 2.0 ppm.

Based upon review of the data supporting the petition summarized in the Notices of Filing, EPA has modified the tolerance level needed for the cucurbit vegetable group 9. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for triflumizole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with triflumizole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The liver is the primary target organ of triflumizole. Liver effects were seen in rat and mouse subchronic and chronic/carcinogenicity studies. Subchronic effects included increased absolute and relative liver weights, accumulation of fat droplets, and slight hepatocyte centrilobular swelling. With increased length of exposure, the types of microscopic lesions noted increased in number and severity. Chronic effects included hepatocyte fatty vacuolization; hepatocyte hypertrophy, focal inflammation, and necrosis; fatty degeneration; eosinophilic foci of hepatocyte alteration; hepatic nodules; bile duct hyperplasia; and hyaline degeneration/fibrosis of the bile duct. The dog was less sensitive to the effects of triflumizole. In the dog chronic study, effects included increased liver weights, increased serum alkaline phosphatase levels, and a macroscopic

hepatic lobular pattern and granular texture. A very mild, macrocytic anemia was also noted and was most likely secondary to liver effects.

Triflumizole is classified as not likely to be carcinogenic to humans, based on a weight of evidence determination including the lack of evidence of carcinogenicity in studies in rats and mice and the absence of a mutagenicity concern.

The oral rat developmental study showed an increased qualitative susceptibility of the fetus to triflumizole *in utero*. Decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight and increased incidences of cervical ribs was seen in the fetuses at the same doses at which maternal toxic effects were noted. In addition, increased incidences of 14^{th} rudimentary ribs were observed at the next highest dose. Maternal toxic effects in the rat were decreased body weight gain and decreased food consumption, increased placental weight, and increased maternal spleen and liver weights.

No increased susceptibility of the fetus was noted *in utero* in the rabbit developmental study. Fetal effects included increased fetal and litter incidences of lumbar ribs and decreased placental weights, which was also included as a maternal toxic effect. Maternal toxic effects in the rabbit included decreased body weight gain, decreased food consumption, and decreased placental weights.

In the 3-generation reproductive toxicity study in the rat, offspring effects included decreased pup weights, survival indices, and litter sizes in both F_3 litters, reduced litter size in the F_{1a} litter, increased total-litter mortality in the F_{3a} litter, and developmental effects in the F_{1b} and F_{2b} progeny. Reproductive toxicity, manifested as increased gestation length, was increased in the F_0 dams which were pregnant with F_1

offspring. Increased gestation length can be due to either effect in the dams and/or the offspring, and this alteration in normal reproductive function can result in adverse consequences in both dams and offspring. Accordingly, there is no increased quantitative susceptibility of the fetus. There is increased qualitative susceptibility in pups; however, a clear no-observed-adverse-effect-level (NOAEL) for this effect was established for these effects, and risk assessment endpoints and points of departures (PODs) were selected which are protective for these effects.

In acute oral toxicity studies in the rat and mouse and an acute inhalation study in the rat, animals developed neurotoxic signs within 30 to 60 minutes of administration, which resolved within 24 hours in surviving animals. Signs included ataxia, hypotonia, ventral positioning, urinary incontinence, decreased respiration and heart rates, decreased locomotor movement, lacrimation, salivation, ptosis, and/or rhinorrhea. No treatment-related histopathological effects were found in surviving animals. In the chronic rat study, convulsions were observed sporadically in all dosage groups, but the incidences were significantly higher in the high-dose females. The majority of the convulsions were noted within the first year. Cholinesterase activity was also affected during the first year of the study, but not in a consistent manner. High-dose males had decreased plasma and erythrocyte cholinesterase activity while high-dose females had decreased plasma cholinesterase activity only. There were no treatment-related effects on cholinesterase activity in the brain in either sex at any dose and no neuropathology was noted. No neurotoxic effects were observed in the rat subchronic oral toxicity study or the mouse subchronic oral toxicity and carcinogenicity studies.

The evidence does not support the need for a developmental neurotoxicity (DNT) study. This conclusion is supported by lack of neurotoxic signs noted in the rat subchronic study at any dose, and in the adult or offspring in the developmental and reproductive toxicity studies in the rat. In an immunotoxicity dietary study in female Bagg Albino (BALB/c) mice, a significant decrease in the anti-sheep red blood cells immunoglobulin M (anti-SRBC IgM) response was observed at a dose level of 285.7 milligrams/kilograms/day (mg/kg/day). The NOAEL was 28.6 mg/kg/day. The results of the immunotoxicity study do not impact the PODs selected for dietary and non-dietary exposure risk assessments.

Specific information on the studies received and the nature of the adverse effects caused by triflumizole as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled "Triflumizole: Human-Health Risk Assessment for the Proposed Uses on Greenhouse-Grown Tomato and Cucumber; Pome Fruit Group 11-10, Small Fruit Vine Climbing except Fuzzy Kiwifruit Subgroup 13-07F and Low Growing Berry Subgroup 13-07G, Except Cranberry" on pp. 33-36 in docket ID number EPA-HQ-OPP-2012-0949.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological PODs and levels of concern (LOCs) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses

in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (UF) are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for triflumizole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1.--SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TRIFLUMIZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Developmental Toxicity Study–Rat Developmental LOAEL = 35 mg/kg/day based on decreased numbers of viable fetuses, increased dead or resorbed fetuses, increased numbers of late resorptions, decreased fetal body weight, and increased incidences of cervical ribs
Acute dietary (General population including infants and children)	NOAEL = 25 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day	Acute Neurotoxicity Study–Rat LOAEL = 100 mg/kg/day based on FOB findings (neuromuscular impairment) and decreased locomotor activity

Chronic dietary (All populations)	LOAEL= 3.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 3x UF_L	Chronic RfD = 0.012 mg/kg/day cPAD = 0.012 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Study–Rat Based on liver toxicity (eosinophilic foci in male rats and fatty vacuolation and inflammation and necrosis in female rats).
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 3.5 mg/kg/day (dermal absorption rate = 3.5% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Multi-generation Reproduction Study–Rat LOAEL = 8.5 mg/kg/day based on decreased pup body weight, mortality, reduced litter size, and increased incidence of hydroureter and space between the body wall and organs were observed at 8.5 mg/kg/day. In addition, gestation length was increased in the dams of F_{1a}, F_{2a}, and F_{3a} intervals at the LOAEL of 8.5 mg/kg/day.
Inhalation short-term (1 to 30 days)	Oral study NOAEL = 3.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Multi-generation Reproduction Study–Rat LOAEL = 8.5 mg/kg/day based on decreased pup body weight, mortality, reduced litter size, and increased incidence of hydroureter and space between the body wall and organs were observed at 8.5 mg/kg/day. In addition, gestation length was increased in the dams of F_{1a}, F_{2a}, and F_{3a} intervals at the LOAEL of 8.5 mg/kg/day.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based a weight of evidence determination including the lack of evidence of carcinogenicity in studies in rats and mice and the absence of a mutagenicity concern.		

FOB = functional observational battery. FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to triflumizole, EPA considered exposure under the petitioned-for tolerances as well as all

existing triflumizole tolerances in 40 CFR 180.476. EPA assessed dietary exposures from triflumizole in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.
Such effects were identified for triflumizole and as noted in Table 1of this unit, separate acute endpoints and PODs were selected for females of child-bearing age (13-49) and the general population including infants and children. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). A conservative acute dietary assessment was conducted using tolerance-level residues, and 100 percent crop treated (PCT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, a partially refined chronic dietary assessment was conducted using average residues from supervised field trials, and PCT estimates for currently registered commodities.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that triflumizole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been

measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

Apple: 25%; cantaloupe: 10%; cherry: 25%; cucumber: 2.5%; filbert: 5%; grape: 5%; honeydew: 15%; pear: 45%; pumpkin: 5%; squash: 5%; strawberry: 25%; and watermelon: 5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the

Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which triflumizole may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for triflumizole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of triflumizole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of triflumizole for acute exposures are estimated to be 98 parts per billion (ppb) for surface water and 3.1 ppb for ground water and for chronic exposures are estimated to be 22 ppb for surface water and 3.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 98 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 22 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Triflumizole is currently registered for the following uses that could result in residential exposures: As a foliar spray by home owner and commercial applicators to landscape grown trees, shrubs, and vines and also for use on residential/non-commercially grown trees/vines bearing apples, pears and grapes.

EPA assessed residential exposure using the following assumptions: For residential handlers, short-term dermal and inhalation exposures are expected for triflumizole activities associated with use on ornamental plants and bearing pome fruit trees. The dermal and inhalation endpoints are based on the same toxicological effect for triflumizole, and therefore the MOEs were combined to determine a total risk estimates. For post-application, there is the potential for short-term dermal exposure for adults and children (6-11 years old), exposed as a result of being in an environment that has been previously treated with triflumizole on landscape ornamentals. Post-application exposure from triflumizole use on landscape ornamentals for children (1-2 years) is expected to be negligible based on the following factors:

• Children young enough to exhibit hand-to-mouth behavior would not typically play in ornamental beds or tree plots.

• If present, leaf to skin residue transfer would be negligible because of the minimal frequency and duration of contact.

The residential handler exposure for adults from the back pack sprayer broadcast use of triflumizole to gardens and trees represents the highest estimated risk, and was therefore combined with the chronic dietary exposure for adults (general U.S. population), to estimate the highest aggregate exposure and risk.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found triflumizole to share a common mechanism of toxicity with any other substances, and triflumizole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that triflumizole does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different

additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is evidence of increased qualitative susceptibility following *in utero* exposure to rats in a developmental study. Developmental toxicity resulted in fetal death as compared to maternal toxicity which included decreases in body weight gain and food consumption and increases in placental, spleen, and liver weights.

No quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rabbits in a developmental study. In the developmental rabbit study, a cesarean section was performed with evaluation of 24-hour fetal survival. At this interval, fetal survival was decreased. EPA does not consider this finding to indicate an adverse effect because a cesarean section with 24-hour fetal survival is more an indicator of fetal endurance after being removed from the womb than a measurement of treatment-related effects on fetal viability and, thus, is not appropriate to use to ascertain fetal susceptibility. For similar reasons, such an endpoint survival is not a standard measurement in the guideline developmental toxicity protocols. In addition, the decreased 24-hour fetal survival occurred in isolation and only at a high dose level (100 mg/kg/day) which is 10-fold higher than the NOAEL of 10 mg/kg/day selected for the acute dietary (females 13-49 years of age) exposure scenario for which this endpoint might be pertinent. Further, the 24-hour fetal survival was not replicated in a second developmental rabbit guideline study.

Evidence of increased qualitative susceptibility in pups was evident in the 3-generation reproductive toxicity study in the rat; however, the use of the NOAEL of 3.5

mg/kg/day (offspring and reproductive effects) for incidental oral scenarios and short-term dermal and inhalation scenarios is protective of potential toxicity (observed in the developmental and 2-generation reproductive toxicity studies) following pre- and postnatal exposures.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF for the acute risk assessment, and short-term dermal and inhalation exposure scenarios is removed (1X), and for chronic risk assessment is reduced to 3X. A 3X FQPA SF is retained for the chronic RfD because it is derived from the use of a LOAEL established in the combined chronic toxicity/carcinogenicity study in rats. A 3X rather than a 10X is adequate for the FQPA SF for the reasons provided below:

• For this chemical, the liver is the most sensitive target organ and the histopathological lesions seen in the target organ is used as the endpoint of concern.

• The Agency is confident that the extrapolated NOAEL of 1.2 mg/kg/day (LOAEL of 3.5mg/kg/day ÷ 3 UF_L (use of a LOAEL to extrapolate a NOAEL) = 1.2 mg/kg/day) would be protective of liver effects in this species because the observed liver effects were minimal in severity and did not progress into malignancy (i.e., no liver tumors were seen) even after 2-years of treatment in either sex of rats.

• Retention of the 3X UF_L results in an extrapolated NOAEL of 1.2 mg/kg/day (LOAEL 3.5 mg/kg/day ÷ 3 UF_L= 1.2 mg/kg/day). This value, at a minimum, is approximately 10-fold lower than all the NOAELs established in the database with the other studies as shown in this unit.

The FQPA SF provides adequate protection of infants and children based on the following findings:

i. The toxicity database for triflumizole is complete. Although no subchronic inhalation data is available EPA has waived that data requirement. In determining the need for a subchronic inhalation study, EPA's weight of evidence decision process included both hazard and exposure considerations as well as incorporation of a presumed 10X Database Uncertainty Factor (UFdb) for the lack of this study. Specifically, with regard to exposure considerations, the Agency's LOC in the evaluating the need for the subchronic inhalation study is a MOE of 1,000 for inhalation exposure, which includes the 10X inter-species extrapolation factor, 10X intra-species variation factor, and the 10X UFdb. For trifumizole, residential inhalation exposures resulted in MOEs higher than the LOC of 1,000 when using an oral POD. This indicates that the lack of an inhalation study does not reduce the overall confidence in the risk assessment or result in an uncertainty (i.e., the study will not provide a POD sufficiently low to result in a risk of concern). Because EPA's decision to waive the subchronic inhalation study essentially incorporates an additional 10X UFdb (i.e., the study was only waived because risks were at least 10X lower than required by use of the inter- and intraspecies safety factors), a second additional 10X FQPA SF is not being retained for the protection of infants and children due to the absence of this study.

ii. Signs of neurotoxicity were seen in the acute oral and inhalation studies in the rat and mouse. Signs of neurotoxicity (neuromuscular impairment and decreased locomotor activity) were noted in the acute neurotoxicity study at mid and high doses. As a result, the endpoint from this study was used to assess acute dietary risks from one-

day exposures to triflumizole in the diet of the general population. There were no treatment-related neuropathological findings observed in either sex in the acute neurotoxicity study. No evidence of neurotoxicity was seen in the submitted subchronic neurotoxicity study. Likewise, neuropathological evaluation of study animals in the subchronic neurotoxicity study did not reveal any treatment-related histological effects of the central and peripheral nervous systems. A DNT study is not required based on the lack of neurotoxicity in the rat subchronic neurotoxicity study, and in the adult or offspring in the developmental and reproductive toxicity studies in the rat.

iii. As noted in Unit III.D.2., there is evidence of increased qualitative susceptibility following *in utero* exposure to rats in a developmental study and pre- and or postnatal exposure in a 3-generation reproductive toxicity study in the rat; however, there are no residual uncertainties, and the use of associated RfDs will be protective of the pre- and postnatal toxicity following an acute dietary exposure, and short-term dermal and inhalation exposures.

No quantitative or qualitative evidence of increased susceptibility was seen following *in utero* exposure to rabbits in a developmental study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment utilizes tolerance-level residues, Dietary Exsposure Evaluation Model (DEEM 7.81) default processing factors (where available), and 100 PCT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated. The chronic dietary food exposure assessment utilizes average field trial residues, and percent crop treated information for established tolerances. Some empirical processing factors were used in

the chronic assessment along with DEEM 7.81 default processing factors (where available). The chronic assessment is partially refined; however, since it is based on reliable, high-end data, it will not underestimate exposure/risk.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to triflumizole in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children 6-11 years old and expects post application exposure for children below 6 years to be negligible. These assessments will not underestimate the exposure and risks posed by triflumizole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, EPA performed separate acute risk assessments for females 13 to 49 years old and for the general population, including infants and children, based on different endpoints and aPADs. For females aged 13-49, acute dietary exposure to triflumizole from food and water will occupy 66% of the aPAD chosen for that population subgroup. For the general population and population subgroups other than females aged 13-49, acute dietary exposure to triflumizole is greatest for children 1-2 years old. That subgroup will occupy 40% of the applicable aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to triflumizole from food and water will utilize 39% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of triflumizole is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Triflumizole is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to triflumizole.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined worst case scenario (adult handlers) for short-term food, water, and residential exposures result in an aggregate MOE of 180 and an aggregate MOE of 600 for children 6-11 years old. Because EPA's LOC for triflumizole is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however**,** triflumizole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus

chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for triflumizole**.**

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, triflumizole is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to triflumizole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with nitrogen phosphorous detector (GC/NPD); Method I in PAM Vol. II) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is

recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for triflumizole.

C. Response to Comments

A comment was received that opposed the establishment of these tolerances. Part of the comment opposed the manufacturing and selling of this product due to potential effects on the environment. This is considered irrelevant because the safety standard for approving tolerances under FFDCA section 408 focuses on potential harms to human health and does not permit consideration of effects on the environment. Another part objected to the proposed tolerances because of the amounts of pesticides/toxic chemicals already consumed and carried by the American population. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by FFDCA section 408 EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

D. Revisions to Petitioned-For Tolerances

Using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures, it was initially determined that the existing cucurbit vegetable group 9 tolerance of 0.5 should be increased to 0.8 ppm. However, if the crop group 9 tolerance was to be increased to 0.8 ppm, the U.S. tolerance will be higher than

the Canadian MRL of 0.5 ppm. After re-examining the residue data, EPA is confident that the 0.5 ppm level will be high enough to cover residues from maximum use under the pesticide registration, and therefore, in order to remain aligned with Canada, the existing cucurbit vegetable group 9 tolerance will remain at 0.5 ppm.

V. Conclusion

Therefore, tolerances are established for residues of triflumizole, 1-[1-((4-chloro-2-(trifluoromethyl) phenyl)imino)-2propoxyethyl]-1*H*-imidazole, in or on berry, low growing, subgroup 13-07G at 2.0 ppm; fruit, pome, group 11-10 at 0.5 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.5 ppm; and. tomato at 1.5 ppm. In addition, due to the establishment of these tolerances, the existing tolerances for apple, pear, grape, and strawberry are removed as unnecessary.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 25, 2014.
Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.476:

a. Remove the commodities “Apple,” “Grape,” “Pear,” and “Strawberry” from the table in paragraph (a)(1).

b. Add alphabetically the following commodities to the table in paragraph (a)(1).

The amendments read as follows:

§ 180.476 Triflumizole; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Berry, low growing, subgroup 13-07G, except cranberry	2.0
* * *	* *
Fruit, pome, group 11-10	0.50
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.5
* * *	* *
Tomato	1.5
* * *	* *

* * * * *

[FR Doc. 2014-04862 Filed 03/04/2014 at 8:45 am; Publication Date: 03/05/2014]